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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,470	10/15/2003	Andrew Thomas Forsberg	47563.0010	6641

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/686,470	Applicant(s) FORSBERG ET AL.	
	Examiner Michael G. Mendoza	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,11-15 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,11-15 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

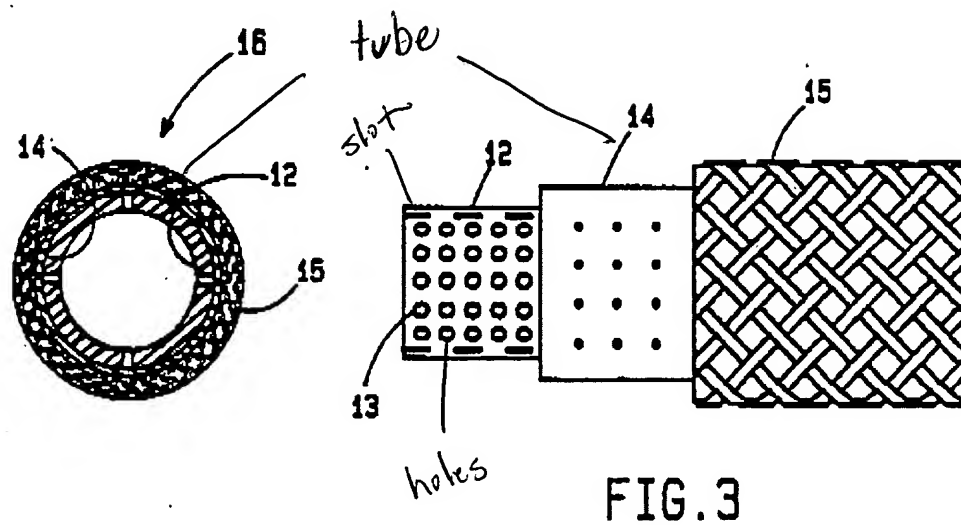
1. Applicant's arguments filed 17 October 2005 have been fully considered but they are not persuasive.
2. In response to applicant's argument that does not teach a "collagen deployment assembly", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
3. In response to applicant's arguments, the recitation the device is a "collagen deployment assembly" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).
4. In response to applicant's argument that Recla does not teach "the tube adapted to deliver and deploy a collagen", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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The structural limitation of a tube is met by Recla and is fully capable of delivering and deploying a collagen. The Examiner points out that "a collagen" is not positively claimed and is not given any patentable weight. The Examiner suggests rewording the claims to positively claim "a collagen"

5. In response to applicant's argument that Recla does not teach "means for wetting adapted to allowing a solution to wet the collagen prior to deployment", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The structural limitation of "means for wetting" is met by Recla and is fully capable of allowing a solution to wet the collagen prior to deployment.

6. In response to applicant's argument that Recla does not teach "slots", the Examiner points out the in the Non-final office action 14 July 2005 the Applicant was directed to fig. 3 which shows all of the claimed structural limitations. Figure 3 clearly shows a tube, at least one perforation, a hole, a slot, a plurality of perforations, a combination of slots and holes, and the plurality of perforation comprise a predefined pattern.



7. Applicant's arguments with respect to claim 15 have been considered but are moot in view of the new ground(s) of rejection. The Applicant has amended the claim to change "a collagen" to "a collagen sponge". The amendment has changed the scope of the claim requiring new consideration and an updated search. A new ground(s) of rejection is made in view of Pavcnik et al. US 2003/0051735.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Recla 5301538.

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10. Recla teaches an assembly, comprising: a tube; at least one perforation; wherein the at least one perforation comprises a hole; wherein the at least one perforation comprises a slot; wherein the at least one perforation comprises a plurality of perforations; wherein the plurality of perforations comprise a combination of slots and holes; wherein the plurality of perforations comprise a predefined pattern; at least one perforation comprises at least one slot arranged at the distal end of the tube and at least one hole arranged between the at least one slot and the proximate end of the tube (fig. 3); and at least one membrane, the at least one membrane for covering the at least one perforation (col. 3, lines 65-68).

11. Claims 15 and 18-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Pavcnik et al. US 2003/0051735.

12. Pavcnik et al. teaches an apparatus, comprising: a vascular closure device, comprising: a collagen sponge 11; a carrier tube 27; at least a part of the collagen sponge resides inside the carrier tube (figs. 5 –7, 9, & 16); and at least one perforation 160 & 162 in the carrier tube; wherein the at least one perforation is at least one of a hole and a slot, wherein the at least one perforation has at least one shape; wherein the at least one shape comprises at least one of a triangle, a circle, a square, a rectangle, a trapezoid, and an ellipse.

13. Claims 15, 18-21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. 5282827.

14. As to claims 15 and 18-21, Kensey et al. teaches an apparatus, comprising: a vascular closure device, comprising: a collagen sponge 30; a carrier tube (see figs. 2,

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3, 7, 11-18, 19-23, & 26-33); at least a part of the collagen sponge resides inside the carrier tube (fig. 11); and at least one perforation 304 in the carrier tube; wherein the at least one perforation is at least one of a hole and a slot, wherein the at least one perforation has at least one shape; wherein the at least one shape comprises at least one of a triangle, a circle, a square, a rectangle, a trapezoid, and an ellipse.

15. As to claim 22, Kensey et al. teaches an apparatus comprising: a tissue puncture closure device comprising: an anchor; a suture attached to the anchor; a collagen sponge slidably attached to the suture adjacent to the anchor (col. 5, lines 17-37); a carrier tube (see figs. 2, 3, 7, 11-18, 19-23, & 26-33) housing the collagen sponge, the carrier tube comprising at least one perforation, the at least one perforation 304 providing a pathway from an external side of the carrier to the collagen sponge.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM


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PRIMARY EXAMINER